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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,636	07/10/2003	Jay A. Warren	279.044US1	3513

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SCHWEGMAN, LUNDBERG & WOESSNER/BSC-CRM
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MINNEAPOLIS, MN 55402

EXAMINER

ALTER, ALYSSA MARGO

ART UNIT	PAPER NUMBER
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3762

NOTIFICATION DATE	DELIVERY MODE
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01/26/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
request@slwip.com

Office Action Summary	Application No. 10/615,636	Applicant(s) WARREN, JAY A.	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 24-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 39-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 April 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 12, 2009 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-23 and 39-46 have been considered but are not persuasive.

The Applicant has argued that claim 7 is definite since the QRS complex and the T wave are both part of the heart signal. However, claim 7 depends on claim 3. Claim 3 narrows scope of the heart signal to the QRS complex. This sensing of the QRS complex excludes the T wave (i.e., only Q-wave, R-wave, and S-wave). Therefore, since claim 7 is dependant on claim 3, it is unclear how the T wave is determined.

The Applicant also argues that Seguin et al. does not disclose "a detected pacing therapy event or a detected evoked or a detected intrinsic heart chamber contraction event of the heart signal". However, Seguin et al. does disclose QRS detection markers for detecting the QRS complex in the ECG signal. Therefore,

Seguine et al. does in fact detect an evoked or an intrinsic heart chamber contraction event of the heart signal.

Additionally, the Applicant argues that the circuit of Seguine et al. does not become temporarily less sensitive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the sensing circuit can remain capable of continually sensing throughout the change in frequency response) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the claim merely recites that "sensing circuit is configured to trigger a frequency response that is temporarily less sensitive" and does not mention continued sensing or ceasing sensing.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites a cardiac rhythm management system, but only mentions a sensing circuit. Since there is not means claimed to provide therapy or "management" of a sensed condition, the examiner considers the claim to be incomplete. Furthermore, if there is no recitation of a means for "management" the

examiner recommends changing the preamble of the claim towards a “cardiac monitoring system”.

2. Claim 7 still stands as rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the “QRS complex”, however claim 7 recites “a T-wave”. It is unclear if the Applicant has additional sensing circuitry to detect the T wave or how the T wave is sensed, since the previous claim 3 detects the “QRS complex”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-7, 11-23 and 39-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Seguine et al. (US 6,185,450 B1). Seguine et al. discloses a cardiac rhythm management system with a sensing circuit configured to sense electrical heart signals and having a frequency response that is initiated by a therapy event or event of the heart. Seguine et al. monitors the ECG signal and detects the QRS function through detection marks (e.g., col. 6, lines 51-52). Since the QRS is detected in the ECG signal, Seguine et al. detects an evoked or an intrinsic heart chamber contraction

event of the heart signal and thus the frequency response is initiated by an evoked or an intrinsic heart chamber contraction event.

Also, “the monitoring circuit includes an amplifier and a switch for switching the frequency response curve of the monitoring circuit. In a first position, the switch causes the monitoring circuit to have a slow frequency response curve, which allows for accurate monitoring of ECG waveforms. In a second position, the switch causes the monitoring circuit to have a fast frequency response curve, which allows the amplifier of the monitoring circuit to quickly be brought out of saturation” (abstract, lines 4-12).

Additionally, “the amplifier of the monitoring circuit is brought out of saturation according to an adjustment routine. The adjustment routine consists of initially setting the duty cycle of the pulse waveform control signal to a minimum so as to quickly bring the amplifier out of saturation. The duty cycle is then increased in incremental steps until a maximum duty cycle is achieved. The incremental steps may be predetermined or they may be customized according to feedback from the amplifier” (col.3, lines 1-10).

Therefore the sensing circuit is temporarily less sensitive to detecting signals and then is followed by a gradual adjustment to become more sensitive.

Additionally, “when the adjustment routine for the duty cycle of the pulse waveform is to be customized according to feedback from the amplifier, a low pass filter is added so as to form an envelope filter” (col. 3, lines 11-15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3762

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seguire et al. (US 6,185,450 B1). Seguire et al. discloses the claimed invention except for the range of time for the first time period. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the range of time for the first time period, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05). Furthermore, a modification to the range of time of the first time period would provide the predictable results of modifying the treatment to meet specific patient needs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Alyssa M Alter/
Examiner
Art Unit 3762